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DEC 14 2004

BIOMET
MANUFACTURING CORP.

## 510(k) Summary

**Applicant/Sponsor:** Arthrotek, Inc.

**Contact Person:** Susan Alexander
Regulatory Specialist

**Proprietary Name:** Bio-Core™ Interference Screw

**Common Name:** Interference Screw

**Classification Name:** Screw, Fixation, Bone (21 CFR §888.3040)

**Legally Marketed Devices to Which Substantial Equivalence Is Claimed:** Resorbable Interference Screw – Arthrotek, Inc. (K041274)
Bone Mulch System – Biomet, Inc. (K993025, K991298, K941941)

**Device Description:** The implant consists of a LactoSorb (85% PLLA/15% PGA) interference screw measuring in diameters from 7-12mm and in lengths from 20 to 30mm. The screw consists of a tapered tip and lattice body design. The internal drive of the screw is a cruciate shape that breaks through the minor diameter of the screw threads allowing an open lattice structure to be created. The internal drive area can be packed with autograft or allograft bone.

**Intended Use:** Indications for the Bio-Core™ Interference Screw include use in soft tissue reattachment procedures in the shoulder, wrist/hand, ankle/foot, elbow, and knee. Specific indications include, but are not limited to, the following:

Shoulder: Bankart repair, SLAP lesion repair, acromio-clavicular separation, rotator cuff repair, capsule repair or capsulolabral reconstruction, biceps tenodesis, deltoid repair.

Wrist/Hand: Scapholunate ligament reconstruction, ulnar/ radial collateral ligament reconstruction.

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P.O. Box 587
Warsaw, IN 46581-0587

SHIPPING ADDRESS
56 E. Bell Drive
Warsaw, IN 46582

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574.267.6639 ■ FAX 574.267.8137 ■ E-MAIL biomet@biomet.com

Ankle/Foot: Lateral stabilization, medial stabilization, Achilles tendon repair/reconstruction, hallux valgus reconstruction, mid- and forefoot reconstruction.

Elbow: Tennis elbow repair, ulnar or radial collateral ligament reconstruction, biceps tendon reconstruction.

Knee: Extra-capsular repair, medial collateral ligament (MCL) repair, lateral collateral ligament (LCL) repair, posterior oblique ligament repair, joint capsule closure, iliotibial band tenodesis reconstruction, patellar ligament/tendon repair, vastus medialis obliquus (VMO) muscle advancement.

In addition to the above indications, the 7.0, 8.0, 9.0, 10.0, 11.0, and 12.0 mm screws are indicated for the following uses:

1. To provide interference fixation of patellar bone-tendon-bone grafts in anterior cruciate ligament (ACL) reconstruction;
2. To provide interference fixation during femoral and/or tibial fixation in anterior cruciate ligament reconstruction using a soft tissue graft (semitendinosus, gracilis); and
3. To provide interference fixation during posterior cruciate ligament (PCL) reconstruction.

**Summary of Technologies:** The Bio-Core™ Interference Screw has the same intended use and is made of a similar material and design as the resorbable predicate devices (K041274).

**Non-Clinical Testing:** Mechanical testing was done on the Bio-Core™ Interference Screw. This testing indicated that the Bio-Core™ Interference Screw was substantially equivalent to the predicate devices.

**Clinical Testing:** Clinical testing was not required for these components to support substantial equivalence.

*All trademarks are property of Biomet, Inc., with the exception of the following:*
*Bio-Core™ Interference Screw and Gentle Threads™ are trademarks of Arthrotek, Inc.*
*Tyvek® is a trademark of E.I. dePont de Nemours and Company*

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 14 2004

Ms. Susan Alexander
Regulatory Specialist
Biomet, Inc.
56 East Bell Drive
P.O. Box 587
Warsaw, Indiana 46581-0587

Re: K042552
Trade/Device Name: Bio-Core™ Interference Screw
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: HWC
Dated: September 17, 2004
Received: September 21, 2004

Dear Ms. Alexander:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

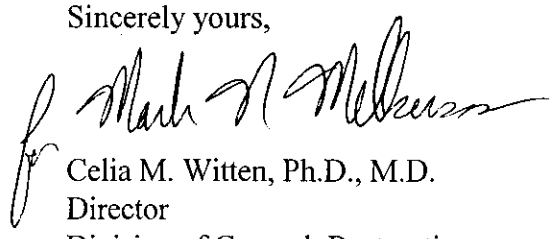
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

## Indications for Use

510(k) Number: K042552

Device Name: **Bio-Core™ Interference Screw**

Indications For Use: Indications for the Bio-Core™ Interference Screw include use in soft tissue reattachment procedures in the shoulder, wrist/hand, ankle/foot, elbow, and knee. Specific indications include the following:

Shoulder: Bankart repair, SLAP lesion repair, acromio-clavicular separation, rotator cuff repair, capsule repair or capsulolabral reconstruction, biceps tenodesis, deltoid repair.
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Ankle/Foot: Lateral stabilization, medial stabilization, Achilles tendon repair/reconstruction, hallux valgus reconstruction, mid- and forefoot reconstruction.
Elbow: Tennis elbow repair, ulnar or radial collateral ligament reconstruction, biceps tendon reconstruction.
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3. To provide interference fixation during posterior cruciate ligament (PCL) reconstruction.

Prescription Use Yes AND/OR Over-The-Counter Use No
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhan

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K042552